ITCH X- benzyl alcohol/pramoxine hydrochloride gel
BF ASCHER AND CO INC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Itch-X Gel

Active ingredients.....Purpose

Benzyl alcohol 10%.....Topical analgesic
Pramoxine hydrochloride 1%.....Topical analgesic

Use

Temporarily relieves pain and itching associated with insect bites, minor burns, sunburn, minor cuts, scrapes, minor skin irritations, hives and rashes due to poison ivy, poison oak, or poison sumac

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Warnings

- For external use only.
- Avoid contact with eyes.

Do not use

- on open wounds, damaged, or blistered skin.
- for vaginal, genital, or rectal itching.
- on children under 2 years of age unless under the advice and supervision of a physician.

Stop use and ask a doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

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If pregnant or breast-feeding, ask a health professional before use.

Keep this and all drugs out of reach of children. In case of ingestion, get medical help or contact a poison control center immediately.

Directions

- adults and children 2 years and older - apply to affected area not more than 3 or 4 times daily
- children under 2 years - consult a physician

Other information

- store at 59°-86° F (15°-30° C) in a dry place
- mfd. in the USA for B.F. Ascher & Co., Inc.

Inactive ingredients: aloe barbadensis leaf juice (aloe vera gel), blue 1, butylene glycol, carbomer, citric acid, diazolidinyl urea, iodopropynyl butylcarbamate, potassium sorbate, SD alcohol 40, sodium benzoate, sodium sulfite, styrene/acrylates copolymer, tetrahydroxypropyl ethylenediamine, and water

Questions? Call 1-800-324-1880, 7:30am - 4:00pm Central, M - F, or visit bfascher.com

Itch-X Gel PDP

ITCH X

benzyl alcohol/pramoxine hydrochloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0225-0495
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZYL ALCOHOL (UNII: LKG8494WBH) (BENZYL ALCOHOL - UNII:LKG8494WBH)	BENZYL ALCOHOL	10 g in 100 g
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALCOHOL (UNII: 3K9958V90M)	
ALOE (UNII: V5VD430YW9)	
WATER (UNII: 059QF0KO0R)	
EDETOL (UNII: Q4R969U9FR)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM SULFITE (UNII: VTK01UQK3G)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0225-0495-33	35.4 g in 1 TUBE; Type 0: Not a Combination Product	09/19/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/19/2014	

Labeler - BF ASCHER AND CO INC (003854403)

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